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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,818	01/09/2002	David R. Elmalch	MGA-004.25	2433

25181 7590 03/25/2005

FOLEY HOAG, LLP  
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EXAMINER

JONES, DAMERON

ART UNIT PAPER NUMBER

1616

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/530,818

**Applicant(s)**

ELMALEH ET AL.

**Examiner**

D. L. Jones

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005.  
2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 8-12 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☒ Claim(s) 1 and 8-12 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **WITHDRAWAL OF FINALITY**

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

### **CLARIFICATION OF RECORD**

2. The following action is deemed necessary in order to clarify what is being claimed in each group listed as a targeting moiety. For example, in the prior office action, prior art directed to antibodies was cited. However, while , for example, colony stimulating factors includes GM-CSF and CSF-1 and receptors and antibodies thereof (see Applicant's specification, page 3, lines 9-10), in the interview with Applicant on 3/3/05, it was set forth that the instant invention as amended excludes antibodies. As a result, colony stimulating factors are not encompassed in the antibody art cited or the claims as amended. Thus, each targeting moiety is distinct for another and contain no overlapping components.

### **RESTRICTION INTO GROUPS**

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1 and 8-12, drawn to a cardiovascular imaging agent, method of imaging, and kit comprising an imaging agent wherein the targeting components are cells, classified in class 424, subclass 9.4.
  - II. Claims 1 and 8-12, drawn to a cardiovascular imaging agent, method of imaging, and kit comprising an imaging agent wherein the targeting

components are colony stimulating factors, classified in class 424, subclass 9.4.

- III. Claims 1 and 8-12, drawn to a cardiovascular imaging agent, method of imaging, and kit comprising an imaging agent wherein the targeting component is platelet factor 4, classified in class 424, subclass 9.4.
- IV. Claims 1 and 8-12, drawn to a cardiovascular imaging agent, method of imaging, and kit comprising an imaging agent wherein the targeting component are growth factors, classified in class 424, subclass 9.4.
- V. Claims 1 and 8-12, drawn to a cardiovascular imaging agent, method of imaging, and kit comprising an imaging agent wherein the targeting components are cytokines, classified in class 424, subclass 9.4.
- VI. Claims 1 and 8-12, drawn to a cardiovascular imaging agent, method of imaging, and kit comprising an imaging agent wherein the targeting component are interferons, classified in class 424, subclass 9.4.
- VII. Claims 1 and 8-12, drawn to a cardiovascular imaging agent, method of imaging, and kit comprising an imaging agent wherein the targeting components are tumor necrosis factors, classified in class 424, subclass 9.4.
- VIII. Claims 1 and 8-12, drawn to a cardiovascular imaging agent, method of imaging, and kit comprising an imaging agent wherein the targeting component are cellular sources of energy for metabolic active plaque formation, classified in class 424, subclass 9.4.

- IX. Claims 1 and 8-12, drawn to a cardiovascular imaging agent, method of imaging, and kit comprising an imaging agent wherein the targeting component are lipids and lipid receptors, classified in class 424, subclass 9.4.
- X. Claims 1 and 8-12, drawn to a cardiovascular imaging agent, method of imaging, and kit comprising an imaging agent wherein the targeting moiety is a components of clotting, classified in class 424, subclass 9.4.

**Note:** Claims appearing in more than one group will only be examined to the extent that they read on the elected group.

4. The inventions are distinct, each from the other because of the following reasons: Inventions I-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions which comprise a cardiovascular imaging agent, method of using the agent for imaging, and a kit comprising the imaging agent have distinct targeting moieties. Thus, even though the claims classify the same, a separate search is necessary for each distinct targeting moiety. Furthermore, prior art cited against one targeting moiety would neither anticipate nor render obvious the other targeting moieties.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

### **ELECTION OF SPECIES**

6. Claims 1 and 8-12 are generic to a plurality of disclosed patentably distinct species comprising a cardiovascular imaging agent that comprising a targeting agent and a radionuclide. The targeting moiety may be cells (e.g., smooth muscle cells, leukocytes, lymphocytes), colony stimulating factors (e.g., GM-CSF and CSF-1 and receptors and antibodies thereof), platelet factor 4, growth factors (e.g., transforming growth factors, endothelial growth factors, or growth factors that initiate smooth muscle proliferation), cytokines (e.g., interleukins), interferons (e.g., interferon alpha or interferon gamma), tumor necrosis factors (e.g. tumor necrosis factor alpha), cellular sources of energy for metabolic active plaque formation, lipids (e.g., liposomes), lipid receptors, or components of clotting (e.g., fibrin, thrombin, fibrinogen, factor VIII, factor IX). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

**Note:** Applicant is respectfully requested to elect a species from within the elected group above. In particular, the species should identify specific cell, colony stimulating factor, growth factor, cytokine, interferon, tumor necrosis factor, cellular source of energy for metabolic active plaque formation, component of clotting, , lipid, or lipid receptor.

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7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Due to the complexity of the restriction requirement, telephone call was not made to request an oral election to the above restriction requirement.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

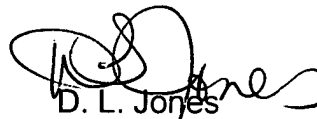
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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617.

The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
D. L. Jones  
Primary Examiner  
Art Unit 1616

March 16, 2005